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Talcott, Tim - SPI; Willmott, Jim-PxL; Kelly, Tom - SPI
Speaker Request for Hearing on Friday July 26, 2002 for Bar Code Labeling for Medical Products...

I would be very interested in making a brief presentation (no more than 1/2 hour) about a possible regulation covering bar coding in the medical device industry on July 26th.

As a mid-sized medical device manufacturer that strives to be current with trends in the industry, we have been bar coding at the case level since mid-1995 to virtually no use in anticipation of bar coding finally "coming of age". We are very concerned that there will be a push to do bar coding at the each level which will incur substantial additional costs for the supplier with modest, if any internal commercial applications and virtually no benefit for patients. We would encourage that if the industry is serious about bar coding, that the regulation cover the entire supply chain. There is real advantage to doing bar coding...that's obvious. But, without the participation of all levels of the supply chain, we can't see benefits arising for patients.

A worthwhile analogy for what needs to happen is the retail industry and Wal-Mart or the auto industry and parts suppliers. When the end of the supply chain, i.e. Wal-Mart and the car companies, declared that all their suppliers must bar code to be a supplier, the supply chain fell in line very quickly, bar coding at the case. Now, the hospital "industry" is not so well organized as Wal-Mart or the major car companies. But, if there were a requirement that they utilize bar coding, then that would force all participants in the supply chain to do bar coding where it will actually be utilized. By all participants, I mean device manufacturers and suppliers as well all distributors.

It is clear that bar coding at the unit of use level can bring significant benefits to patient safety. I don't think that is in dispute. The ongoing issue with bar coding at the each level, even the case level, has been its implementation which has been discussed for nearly 20 years. So, the real message is that the regulation must be comprehensive for the supply chain.

Thank you for considering this topic for the agenda.

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